



Certified Industry Readiness Course in **Regulatory Affairs**

**Best Recommended Certified Course for B. Pharm, M. Pharm Students for
Overall Career Development and for Career Progression in Regulatory Affairs**

Jointly Organized By



About Course



Regulatory affairs is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines.

Through this Certified Course, students and candidates will get the utmost learnings from the Regulatory Affairs. These learnings will help them to get to know the latest understandings of the workings of Regulatory Affairs.

Need & Objective:

- To imbibe and fill in the Knowledge regarding the Current Workings of Indian Pharma Regulatory Affairs Sector.
- To analyse the awareness of Students towards Regulatory Affairs Process
- To help student acquire the required knowledge of Regulatory Affairs from regulatory guidelines to its documentation
- To enhance employability chances by increasing the Technical Knowledge of the Candidates as per Industry Requirements.

Outcome:

- Candidate will be able to identify the needs of Regulatory Affairs Working Situations.
- Candidates will be able to get the understandings of the Regulatory Affairs department of the Industry
- Candidate can learn the basic job responsibilities that Regulatory Affairs Entails

Course Contents

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Session Contents

- Career in Regulatory Affairs: Learnings and Skills
- Introduction to Regulatory Affairs
- Responsibilities of RA Personnel & Difference between Site RA and Corporate RA
- ANDA, NDA
- INDA and Drug Master File
- MAA, 505(2)b Application
- NME, OTC, ASMF
- Orange Book
- Hatch-Waxman Act
- Abbreviations
- Regulatory Bodies and Compliances

Course Mentors:

- **Satish Mahajan, GSK Consumer Private Limited**
LinkedIn Profile: <https://bit.ly/3u2zIIS>
- **Hrishikesh Dhongade, Novartis**
LinkedIn Profile: <https://bit.ly/3tZDyw9>

Execution

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Who can enrol?

- B. Pharm/ M. Pharm Students

Execution Mode:

- CiREE Application

Value Proposition:

- **Unique Course that provides in-depth knowledge regarding Regulatory Affairs**
- **Top-Class Industry Expert: Will Guide & deliver the Session through his own Experience**
- **Fulltime Access to the Course**
- **Certification of Completion**

Certificate Representation:

